UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported)	March 7, 2019

NAVIDEA BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35076	31-1080091
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4995 Bradenton Avenue, Suite 240, Dublin, Ohio	43017
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (614) 793-7500

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 7, 2019, Navidea Biopharmaceuticals, Inc. (the "Company") issued a press release regarding its consolidated financial results for the quarter ended December 31, 2018. A copy of the Company's March 7, 2019 press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in Item 2.02 of this Current Report on Form 8-K, including exhibit 99.1 attached hereto, shall not be treated as "filed" for purposes of the Securities Exchange Act of 1934, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	*Exhibit Description*
99.1	Press Release dated March 7, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Navidea Biopharmaceuticals, Inc.

Date: March 7, 2019

By: /s/ Jed A. Latkin
Jed A. Latkin
Chief Executive Officer, Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Navidea Biopharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results

Conference Call to be held Thursday, March 7, 2019 at 5:00 pm ET

DUBLIN, Ohio--(BUSINESS WIRE)--Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) ("Navidea" or the "Company"), a company focused on the development of precision immunodiagnostic agents and immunotherapeutics, today announced its financial results for the fourth quarter and full year of 2018. Navidea reported total revenues for the quarter of $119,000. Net loss attributable to common stockholders was $3.2 million.

"Navidea had a productive quarter as we advanced the business and our novel imaging pipeline," said Mr. Jed A. Latkin, Chief Executive Officer of Navidea. "While we had many successes this past quarter, we will continue to work hard to advance the science and seek the go ahead from the FDA to commence our pivotal RA diagnostic trials. Our newly reconstituted board and the addition of our new Chief Medical Officer have reinvigorated our efforts to make this company a success."

Fourth Quarter 2018 Highlights and Subsequent Events

- Filed a comprehensive three-part clinical trial proposal for imaging of rheumatoid arthritis with the U.S. Food and Drug Administration ("FDA"), following end-of-Phase 2 discussions
- Presented corporate overviews at the 2018 BIO Investor Forum and the 2018 LD Micro Annual Event
- Presented data on the Manocept platform at the 2018 ACR Annual Meeting and at the 2018 Radiological Society of North American Scientific Assembly and Annual Meeting
- Received notification of acceptance by the NYSE American of the Company's plan to regain compliance with continued listing standards; also received an extension of the deadline to remedy the low stock price to March 31, 2019
- Won dismissal of Platinum litigation
- Announced release of a letter by the FDA to the U.S. Patent and Trademark Office ("USPTO") indicating that the USPTO is allowed to extend the patent for Lymphoseek® through May 2025
- Appointed Adam D. Cutler and S. Kathryn Rouan, Ph.D. to the Navidea Board of Directors
- Hired Michael S. Rosol, Ph.D. as Navidea's Chief Medical Officer

Financial Results

Our consolidated balance sheets and statements of operations have been reclassified, as required by current accounting standards, for all periods presented to reflect the line of business sold to Cardinal Health 414, LLC in March 2017 as a discontinued operation. Accordingly, this discussion focuses on describing results of our operations as if we had not operated the discontinued operation during the periods being disclosed.

- Total revenues for the fourth quarter of 2018 were $119,000, compared to $395,000 in the same period of 2017. The decrease was primarily due to a reduction in grant revenue related to SBIR grants from the NIH supporting Manocept development. Total revenues for the full year of 2018 were $1.2 million, compared to $1.8 million in 2017. The decrease was primarily due to a reduction in grant revenue, offset by increased license revenue related to the sublicense of NAV4694 to Meilleur. Revenue in both years included other revenue from our marketing partners in Europe and China related to development work performed at their request.

- Research and development ("R&D") expenses for the fourth quarter of 2018 were $854,000, compared to $1.7 million in the same period of 2017. R&D expenses for the full year of 2018 were $4.2 million, compared to $4.5 million in 2017. The decrease in both periods was primarily due to net decreases in Manocept development costs for clinical trials, coupled with decreased compensation costs resulting from headcount reduction.
- Selling, general and administrative ("SG&A") expenses for the fourth quarter of 2018 were $1.4 million, compared to $2.2 million in the same period of 2017. SG&A expenses for the full year of 2018 were $7.7 million, compared to $11.2 million during 2017. The net decrease in both periods was primarily due to decreased legal and professional services, as well as decreased general office, insurance, depreciation, rent, and travel expenses, offset by termination costs associated with the resignation of our former CEO in 2018.
- Navidea's net loss attributable to common stockholders for the fourth quarter of 2018 was $3.2 million, or $0.02 per share (basic), compared to a net loss attributable to common stockholders of $4.1 million, or $0.03 per share, for the same period in 2017. Navidea's net loss attributable to common stockholders for the full year of 2018 was $16.1 million, or $0.09 per share (basic), compared to net income attributable to common stockholders of $74.9 million, or $0.47 per share, in 2017.
- Navidea ended the fourth quarter of 2018 with $4.3 million in cash and investments.

Conference Call Details

Investors and the public are invited to dial into the earnings call through the information listed below, or participate via the audio webcast on the company website. Participants who would like to ask questions during the question and answer session will be prompted by the moderator, who will provide instructions.

Event:	Fourth Quarter 2018 Earnings and Business Update Conference Call
Date:	Thursday, March 7, 2019
Time:	5:00 pm (Eastern Time)
U.S. & Canada Dial-in:	877-407-0312
Conference ID:	13687788
Webcast Link:	https://webcasts.eqs.com/navidbioph20190307

The recorded conference call can be replayed and will be available for 90 days following the call, available on the investor relations page of Navidea's corporate website at www.navidea.com.

About Navidea

Navidea Biopharmaceuticals, Inc. (NYSE American: NAVB) is a biopharmaceutical company focused on the development of precision immunodiagnostic agents and immunotherapeutics. Navidea is developing multiple precision-targeted products based on its Manocept™ platform to enhance patient care by identifying the sites and pathways of disease and enable better diagnostic accuracy, clinical decision-making, and targeted treatment. Navidea's Manocept platform is predicated on the ability to specifically target the CD206 mannose receptor expressed on activated macrophages. The Manocept platform serves as the molecular backbone of Tc99m tilmanocept, the first product developed and commercialized by Navidea based on the platform. The development activities of the Manocept immunotherapeutic platform are being conducted by Navidea in conjunction with its subsidiary, Macrophage Therapeutics, Inc. Navidea's strategy is to deliver superior growth and shareholder return by bringing to market novel products and advancing the Company's pipeline through global partnering and commercialization efforts.

For more information, please visit www.navidea.com.

Forward-Looking Statements

This release and any oral statements made with respect to the information contained in this release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things: any future actions by Platinum-Montaur; general economic and business conditions, both nationally and in our markets; our history of losses and uncertainty of future profitability; the final outcome of any pending litigation; our ability to successfully complete research and further development of our drug candidates; the timing, cost and uncertainty of obtaining regulatory approvals of our drug candidates; our ability to successfully commercialize our drug candidates; our expectations and estimates concerning future financial performance, financing plans and the impact of competition; our ability to raise capital sufficient to fund our development and commercialization programs; our ability to implement our growth strategy; anticipated trends in our business; advances in technologies; our ability to comply with the NYSE American continued listing standards; our ability to maintain effective internal control over financial reporting; and other risk factors detailed in our most recent Annual Report on Form 10-K and other SEC filings. You are urged to carefully review and consider the disclosures found in our SEC filings, which are available at www.sec.gov or at http://ir.navidea.com.

Investors are urged to consider statements that include the words "will," "may," "could," "should," "plan," "continue," "designed," "goal," "forecast," "future," "believe," "intend," "expect," "anticipate," "estimate," "project," and similar expressions, as well as the negatives of those words or other comparable words, to be uncertain forward-looking statements.

You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be incorrect. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Contact

Navidea Biopharmaceuticals, Inc.
Jed Latkin, CEO, 614-973-7490
jlatkin@navidea.com

NAVIDEA BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2018 (unaudited)	December 31, 2017
Assets:		
Cash and available-for-sale securities	$ 4,275,151	$ 4,592,610
Accounts and other receivables	21,151	8,137,872
Other current assets	678,215	1,101,923
Guaranteed earnout receivable	-	4,809,376
Other non-current assets	2,034,511	2,139,655
Total assets	$ 7,009,028	$ 20,781,436
Liabilities and stockholders' equity:		
Notes payable, current	$ 316,074	$ 2,353,639
Accrued loss for CRG litigation	-	2,887,566
Other current liabilities	3,062,445	2,827,198
Deferred revenue	700,000	11,024
Other liabilities	532,549	653,679
Total liabilities	4,611,068	8,733,106
Navidea stockholders' equity	1,729,639	11,379,630
Noncontrolling interest	668,321	668,700
Total stockholders' equity	2,397,960	12,048,330
Total liabilities and stockholders' equity	$ 7,009,028	$ 20,781,436

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Twelve Months Ended	
	December 31, 2018 (unaudited)	December 31, 2017 (unaudited)	December 31, 2018 (unaudited)	December 31, 2017
Revenue:				
Royalty revenue	$ 5,505	$ 9,126	$ 15,347	$ 9,126
License revenue	29,535	-	307,174	100,000
Grant and other revenue	84,281	386,013	846,830	1,701,311
Total revenue	119,321	395,139	1,169,351	1,810,437
Cost of revenue	22,825	3,651	96,636	3,651
Gross profit	96,496	391,488	1,072,715	1,806,786
Operating expenses:				
Research and development	854,437	1,748,147	4,221,881	4,513,842
Selling, general and administrative	1,443,661	2,163,226	7,698,135	11,169,951
Total operating expenses	2,298,098	3,911,373	11,920,016	15,683,793
Loss from operations	(2,201,602)	(3,519,885)	(10,847,301)	(13,877,007)
Other income (expense):				
Interest (expense) income, net	(10,565)	24,160	(30,799)	168,971
Change in fair value of financial instruments	-	-	-	153,357
Loss on extinguishment of debt	(1,026,182)	(2,887,566)	(5,291,616)	(4,201,668)
Other, net	(509)	11,917	1,145	(33,339)
Loss before income taxes	(3,238,858)	(6,371,374)	(16,168,571)	(17,789,686)
(Provision for) benefit from income taxes	62,583	201,333	(2,747)	4,062,489
Loss from continuing operations	(3,176,275)	(6,170,041)	(16,171,318)	(13,727,197)
Discontinued operations, net of tax effect:				
Income (loss) from discontinued operations	3,387	(157,920)	1,449	(490,758)
Gain on sale	-	2,269,811	43,053	89,163,811
Net (loss) income	(3,172,888)	(4,058,150)	(16,126,816)	74,945,856
Less loss attributable to noncontrolling interest	(46)	(18)	(379)	(210)
Net (loss) income attributable to common stockholders	$ (3,172,842)	$ (4,058,132)	$ (16,126,437)	$ 74,946,066
(Loss) income per common share (basic):				
Continuing operations	$ (0.02)	$ (0.04)	$ (0.09)	$ (0.08)
Discontinued operations	$ 0.00	$ 0.01	$ 0.00	$ 0.55
Attributable to common stockholders	$ (0.02)	$ (0.03)	$ (0.09)	$ 0.47
Weighted average shares outstanding (basic)	190,035,265	162,053,385	170,535,343	161,592,569
(Loss) income per common share (diluted):				
Continuing operations	$ (0.02)	$ (0.04)	$ (0.09)	$ (0.08)
Discontinued operations	$ 0.00	$ 0.01	$ 0.00	$ 0.53
Attributable to common stockholders	$ (0.02)	$ (0.03)	$ (0.09)	$ 0.45
Weighted average shares outstanding (diluted)	190,035,265	166,465,741	170,535,343	166,016,458